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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------------|------------------|
| 10/701,717 | 11/04/2003 | Jin Po Lee | 532812000200 | 7412 |
| 25225 7590 02/20/2007 MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE SUITE 100 SAN DIEGO, CA 92130-2040 | | | EXAMINER ALEXANDER, LYLE | |
| | | | ART UNIT 1743 | PAPER NUMBER |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 02/20/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/701,717

Applicant(s)

LEE, JIN PO

Examiner

Lyle A. Alexander

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8-15 and 17-24 is/are pending in the application.
- 4a) Of the above claim(s) 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8-15 and 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, 8-15 and 17-20, drawn to an apparatus for analysis of a test device, classified in class 422, subclass 164.
- II. Claims 21-24, drawn to a method of optically scanning, classified in class 359.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process of claims 21 and 23 can be practiced by another and materially different apparatus, such as one that has a defining background area. Claims 22 and 24 can be practiced by a different device that does not contain a test device.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Newly submitted claims 21-24 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: See the above restriction requirement.

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Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-24 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5,8-15, 17 and 19 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Lappe et al. (USP 6,514,461) or Anderson et al. (USP 6,394,952).

Lappe et al. teach a system for automatically testing and digitally recording the test results from a sample. Column 2 lines 38+ teach details about the computer and the cap is transparent or provided with transparent windows to permit external viewing of the test strips. Columns 3-4 lines 46-26 respectively teach capturing, analyzing and recording the test results with a digital camera and computer system that has been read on the claimed computer and scanner. Column 5 lines 41-55 teach a keyed recess(70) that is complementary to the base of the assay device(30) in the base platform(72). The recess(70) has been read on the claimed "template for holding the at least one test device". Column 6 lines 38-46 teach windows(114A,114B,114C) covering the test strip and have been read on the claimed "windows".

Anderson et al. teach a system that will digitally record test results from a test device. Figure 2A teach a device(200) with a window(214) over an immunoassay test

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strip. Column 37 lines 14-28 teach the test strip is held in place between the upper and lower halves(502 and 504 respectively) to be viewable through window(214). This has been read on the claimed template and window. Column 7 lines 58 through column 9 teach optical imaging equipment that will scan the test strip and convert the image into a digital format that facilitates computer analysis using neural networks. This has been read on the claimed computer and scanner.

With respect to new claims 17 and 19, these claims require the template to have a cut out of the window and to expose the entire surface one wants to scan. The Office maintains the above cited prior art teaches both of these limitations.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lappe et al. or Anderson et al.

See Lappe et al. and Anderson et al. supra.

These references are silent to the specific materials of construction and shapes of the templates.

The court decided In re Leshin(125 USPQ 416) that the selection of a material of construction "... based upon its suitability of intended use, would be entirely obvious...". Metal is well known in the art for light shielding and protection from mechanical damage. It would have been within the skill of the art to modify either Lappe et al. or Anderson et

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al. and use a template made of a metal to gain the above advantages and based upon the metal's suitability of intended use.

The court decided In re Dailey(149 USPQ 47) that changes in shape or configuration is a matter of choice. It would have been desirable to change the shape of the template window to accommodate different shaped test devices. It would have been within the skill of the art to modify either Lappe et al. or Anderson et al. and change the shape of the template to accommodate the shape of the test device as such changed are a matter of choice.

Response to Arguments

Applicant's arguments filed 11/20/07 have been fully considered but they are not persuasive.

Applicant argues both Lappe et al. and Anderson do not teach the claimed "... window for temporarily receiving wherein the window has a shape corresponding to the shape of the at least one test device so as to maintain ... a fixed location during scanning...". The Office maintains the instant claim language of "a shape corresponding to" is not restrictive to exactly the same shape as argued by Applicant. The cited prior art teaches a cover/window that corresponds to the shape of the test device to facilitate the external reading/visualization of the test device and had been properly read on the instant claims.

Applicants state the recess(70) taught by Lappe et al. is not configured to fit on the surface of a scanner as required by the instant claims. The Office maintains the device(60) taught by Lappe et al. is the scanner and the recess(70) is configured to fit

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into the scanner/device(60). Lappe et al. have been properly applied to these limitations.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lyle A Alexander
Primary Examiner
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A handwritten signature in black ink, appearing to be 'Lyle A. Alexander', written in a cursive style.